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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,458	12/21/2000	Jorg G. Moser	BJA272C	3984
28184	7590	08/21/2006	EXAMINER GUPTA, ANISH	
BOLESH J. SKUTNIK CERAMOPTEC INDUSTRIES, INC. 515 SHAKER RD. EAST LONGMEADOW, MA 01028			ART UNIT 1654	PAPER NUMBER

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/745,458	Applicant(s) MOSER, JORG G.	
	Examiner Anish Gupta	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 7-19 is/are pending in the application.
 4a) Of the above claim(s) 3,4,7 and 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,8 and 12-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Applicants amendment, filed 6-7-06, is acknowledged. Claims 1, 8-18 were amended, claim 2, 5-6 were canceled, and claim 19 was added. Claims 1, 3-4, 7-19 are pending this Application.

2. In the response, filed 5-17-02, Applicants elected a parachute structure of “cyclodextran.” The therapeutic component was chosen to a photosensitizer such as porphyrin. Applicants also chose the spacer as a beta-amino acid or gamma-amino acid.

A search was conducted for the elected species of cyclodextran with porphyrin and prior art was found that anticipated the species. Claims 1-2, 5-6, 8, 12-18 read on the elected species.

Claims 3-4, 7, 9-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 8, 12-19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For the “action diameter” Applicants argue that “[w]hen the spacer is also used, it will define with the cyclodextrin the action diameter.” It is still unclear as to the “action diameter.” Applicants

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response seems to indicate that when a spacer is used, the action diameter will be achieved. However, base claim 1 does not make reference to a spacer and dependent claims do not indicate whether the spacers recited achieve the desired action diameter.

Applicants have amended the claims to recite “wherein said parachute structure comprises a hydrophilic moiety, namely, a cyclodextrin, which has a defined action diameter.” First it is unclear if the parachute structure is cyclodextrin. “[N]amely, a cyclodextrin” does not specifically indicate that the parachute structure is cyclodextrin. Rather, this allows for other structures beyond cyclodextrin. Thus, the claim is indefinite.

Claim 19 states that the therapeutic is “placed within the cell at a defined distance from the cell membrane.” It is unclear how this is achieved. Modes of administration include injections, transdermal, oral, topical etc.. It is unclear which modes of administration if any have the capability to place the compound “within the cell at a defined distance from the cell membrane.” Furthermore, it is unclear as to what this “defined distance” is since the claim does not define a specific distance.

The rejection is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 8, 12-19 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicants argue that claim 1 has been amended so as to provide the structure for the general terms of “parachute structure” and “therapeutic compound.”

However, since the claim is open to any parachute structure, the concerns raised in the previous office action remain. The functional language of “preselected defined action diameter” does not provide insight into the structure since the “said action diameter is defined by the structure of branching units to which said hydrophilic moieties are bound and the length and structure of said hydrophilic moieties.” The parachute structure comprising hydrophilic moieties. Thus, without knowing the parachute structure, does not know the “preselected defined action diameter.” Further, although the specification does provide examples of what qualify as compounds of the claimed invention, which are limited to a single embodiment in example 1 which is cyclodextran conjugated to bacteriopheophorbide, the specification lacks sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples beyond cyclodextran conjugated to bacteriopheophorbide. The specification is void of any peptides, organic molecules that qualify for the functional characteristics claimed as parachute structures. The specification is limited defining parachute structure as glucosamine and cyclodextrin. There is no disclosure of other compounds that qualify as parachute structures. The specification states that “parachute function may be achieved by other, more bulky hydrophilic structures such as oligosaccharides connected to the branching unit,” but does not exemplify these “bulky hydrophilic structures. The specification is replete generic definitions without specific examples. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does “little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.”). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

The rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 1, 8, 12-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruebner et al. remain rejection for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to a complex comprising a parachute structure, that is a cyclodextran, and a therapeutic compound that is porphyrin.

It is assumed that Applicants are attempting to distinguish the reference by stating that the reference does not teach the use of the compounds as photosensitizers or for PDT. Further, Applicants argue that the paper cited “is primarily about establishing that multiple biotin-avidin containing species bound to photosensitizers could enhance activity of the photosensitizers by bringing a number of photosensitizers to a previously activated cell surface.” Applicants state that article does teach the use of the “biotin-avidin for vectoring purposes.”

Applicants argument have been fully considered but have not been found persuasive.

The claims of the invention are drawn to complex comprising parachute structure, that is a cyclodextran, and a therapeutic compound that is porphyrin. In their response, Applicants

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acknowledge porphyrin photosensitizers can be bound within the cyclodextrin dimers (see page 6 of Applicants response). Thus, Applicants acknowledge that the complex is taught by the prior art. The claims do not recite PDT or photosensitizers. Even where this was a limitation in the claims, since the claims are drawn to products, the intended use of the product is not limiting for patentability. However, the reference does teach cyclodextrin dimers conjugated to porphyrins such as ter-butylphenoxy-ethy-pyropheophorbide-ethyl ester or tri-tert-butylphenoxy-monosulfophenoxy-phthalocyanine (see page 37). The reference states that cyclodextrin dimers bound to porphyrinoid derivatives are suitable for photosensitizers in Photodynamic therapy. Photodynamic therapy (PDT) is also called photoradiation therapy, phototherapy, or photochemotherapy.

Applicants argue with regards to biotin-avidin. However base claim 1 does not provide biotin-avidin as a limitation. Thus, the arguments are not found persuasive.

Rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with

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this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer.

A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claim 1, 8, 12-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-11 of U.S. Patent No. 6,806,28. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Applicants argue that claim 1 does not overlap with the issue claims of the parent Application. Thus, the rejection should be withdrawn.

However, as stated previously, Applicants have amended the claims to recite "wherein said parachute structure comprises a hydrophilic moiety, namely, a cyclodextrin, which as a defined action diameter." It is unclear if the parachute structure is cyclodextrin. "[N]amely, a cyclodextrin" does not specifically indicate that the parachute structure is cyclodextrin. Rather, this allows for other structures beyond cyclodextrin. Thus, the claim is still rejection under the Double Patenting rejection for the reasons set forth in the previous office action.

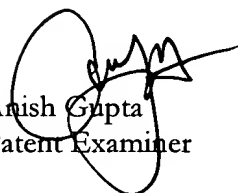
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on

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the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.


Anish Gupta
Patent Examiner